ADDED FEATURES

The Electronic Submissions System (ESS) Portable Document Format (PDF) Smart Forms Version 4.1 have enhanced layouts and consistent functionality in all of the forms. The forms include:

- Notice Of Claimed Investigational Exemption (FDA 3458);
- Notice Of Final Disposition Of Investigational Animals Not Intended For Immediate Slaughter (FDA 3487);
- Notice Of Intent To Slaughter For Human Food Purposes (FDA 3488);
- Request For A Meeting Or Teleconference (FDA 3489);
- Protocol For Non-Clinical Laboratory And Effectiveness Studies (FDA 3536);
- Electronic Submission System Participant Password or Addition (FDA 3538).

These new enhancements are:

- Forms have been upgraded to provide consistent functionality when viewing and completing the forms using Adobe Acrobat 7.0.
- Functionality provided in the ESS PDF Smart Forms Version 4.0 has been retained.

New versions of ESS Smart Forms will be released on November 1, 2005. These forms will operate with all versions of Adobe Acrobat® that the ESS supports (Adobe Acrobat versions 5.x, 6.x and 7.x). The version number for all forms has been changed to version 4.1. Sponsors planning to install Adobe Acrobat version 7.0 <u>must</u> download the version 4.1 forms. These forms may be downloaded from the following web address:

http://www.fda.gov/cvm/esubstoc.html

<u>Version 4.0 forms will not have full functionality when viewed using Adobe Acrobat version 7.</u> Sponsors opening version 4.0 ESS PDF Smart Forms with Adobe Acrobat 7.0 will experience problems when attempting to use the 'Import Data' button. The 'Import Data' button will not work when opening version 4.0 ESS PDF Smart Forms with Adobe Acrobat 7.0. Sponsors not planning on upgrading to Adobe Acrobat 7.0 do not need to download the version 4.1 forms.

Note: The ESS is no longer accepting PDF Smart Forms with a version lower than 4.x.

COMMON FEATURES

Form Features:

- With a few exceptions, fields no longer have a default value; you must now fill in every required field.
- Moving the mouse over the command buttons displays what the command buttons will do.
- Moving the mouse over a data field reveals what the name of the field is, the format of the field, and if the field is optional or required.
- Command button functions are the same on all of the forms.

Form Rules:

- All the fields that are marked required must be filled in before submitting the form to CVM.
- The form must be successfully validated and a password must be applied before being sent to CVM.

Command Buttons at the Top of Each Form

- Each form has the same command buttons located at the top of the form. These command buttons act exactly the same for each form.

| Guidance		Export Data	Import Data	Reset Form
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Center for Veterinary Medicine	Notice of Claimed Investigational Exemption			Form Approved: OMB No. 0910-0117 Expiration Date: 3/31/05

- **Guidance:** This button will open the CVM specific Guidance for the form. Web access is required for this command button to operate correctly.
- **Export Data:** This button saves the form data to an FDF file to disk. Users will be able to specify the filename that the exported data will be saved under. Used in conjunction with the "Import Data" command, users will be able to reduce repetitive typing for common submissions. Certain form fields will not be exported to the export file. The following table lists fields that are not exported:

| FDA Form	Form Field Name	Form Field Number
All Forms (except 3538)	Primary Review Division Mail Code	N/A
All Forms (except 3538)	Previously Submitted to CVM: (Yes/No)	Form Dependent
All Forms (except 3538)	Date Submitted to CVM:	Form Dependent
All Forms (except 3538)	CVM Submission Identifier (Type)	Form Dependent
All Forms (except 3538)	CVM Submission Identifier (Number)	Form Dependent
3458	Protocol Previously Submitted to CVM: (Yes/No)	11
	Date Submitted to CVM:	11a.
	Contract Research Organization Used: (Yes/No)	18 – 18j
3489	Proposed Date(s) and Time(s):	3
	Sub ID (Type)	All entries in multiple documents table
	Sub ID (Number)	All entries in multiple documents table
	Check to Amend Meeting Submission	Multiple documents table

- **Import Data:** This button enables users to import a specific FDF file that was previously saved by clicking the "Export Data" command button. This command will cause the form fields to be populated with the data from the FDF file.
- **Reset Form:** This button clears the forms data fields and resets to standard colors and views. This button is disabled after the form is saved.

Command Buttons at the Bottom of Each Form

- Each form has the same command buttons on the bottom of the last page of the form. These command buttons perform exactly the same for each form.

| 1 - Validate | 2 - Add Password | 3 - Save | 4 - Signature | 5 - Send to CVM |
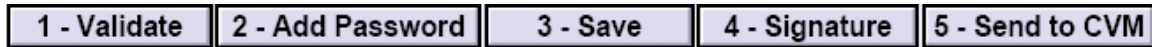
- **Validate:** This button displays detailed information about any errors and missing fields. Each required field that needs information or correction will be color coded. The following graphic shows when the validation process encountered no errors.
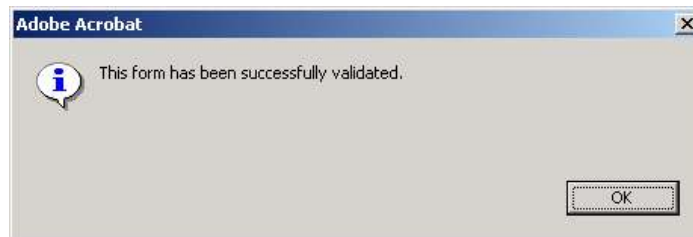
If the validation process uncovered any errors the following screen will be displayed. In addition, the fields that are in error are colored coded to allow for ease of correction.
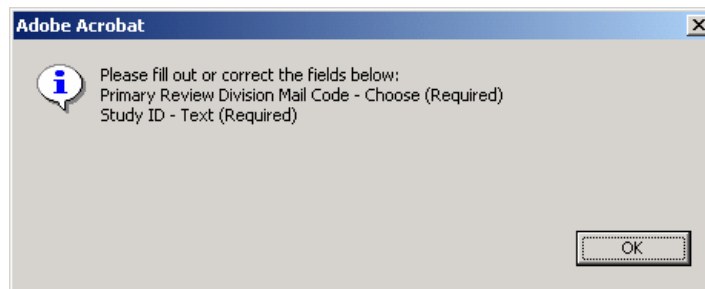
- **Add Password:** By clicking this button, the Menu item 'Document Security' will be executed.
- **Save:** By clicking this button, data validation will be called prior to saving. If errors are encountered, the form fields will be color coded and the 'Save As' menu item will be called. Once the 'Save' button is selected, the 'Reset Form' button is disabled.
- **Signature:** This button causes the Digital Signature field to be visible, and allows the form to be digitally signed. Users will not be able to 'Sign' the document unless the form has been saved with password and all the errors are cleared. **The Signature button is currently disabled.**
- **Send to CVM:** This button e-mails the validated form to CVM. A new e-mail message window opens and the PDF document is sent to CVM as an attachment with the name of the form appearing in the subject line. This only works if your installed Email system supports Adobe building an e-mail message.

Other Command Buttons:

- **Insert Comments:** This button allows a user to insert a PDF document into the Smart Form for the purpose of adding personalized comments. Storage of the comments within the form will be at the end of the form. Multiple documents may be inserted into the form.

<div style="text-align:center">

Insert Comments

</div>

Updated Form Fields For Every Form:

- Changing the 'Country' field from 'USA' to another country causes the corresponding 'State/Prov', 'Postal Code' and 'Phone Number' fields to enter international mode and these fields become optional (the phone number field is always required in the Sponsor Information block whether in USA or international mode). While in international mode, the 'Postal Code' field will accept both alpha and numeric characters. Additionally, the 'Phone Number' field will accept a value in any format.

<div style="text-align:center">

7a. Name:
7c. Address:
7d. Address 2:
7e. City: 7f. State/Prov:
7g. Country: **USA**   7h. Postal Code:
7i. Phone Number:

</div>

- Entering a value of 'USA' into the 'Country' field causes the corresponding 'State/Prov', 'Postal Code' and 'Phone Number' fields to enter USA mode. In USA mode, the 'State/Prov' and 'Postal Code' fields are required and the 'Phone Number' field is optional (the phone number field is always required in the Sponsor Information block whether in USA or international mode). The 'Postal Code' field will accept only numeric characters. The 'Phone Number' field will only accept values in the format of aaa-xxx-nnnn.

FORM FEATURES

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION (FDA 3458)

- Clicking the 'Receipt Information' check box in Section I will set the fields in sections I.7, I.8, and I.9 to optional. Clicking the 'Shipment' check box sets the fields in these sections to their default state.

<div style="text-align:center">

I. ☐ Shipment or ☐ Receipt Information:

</div>

- The form cannot be successfully validated until a value greater than zero is calculated for the 'Total' field in section I.14. This field is calculated as the sum of the 'Treated' and 'Control' fields in section I.14. Entering a value greater than zero into either of these fields will result in successful validation of the required 'Total' field. Section I.15 is calculated the same way.

14. APPROXIMATE NUMBER OF ANIMALS IN THIS STUDY/ TRIAL:
Total: 0   Treated: 0   Control: 0

- Clicking the 'YES' button in sections I.11 or I.18 causes the fields in their corresponding sections to be changeable. The 'Date Submitted to CVM' field in section I.11a is optional, and both fields in section I.11b are required. Clicking the 'NO' button in section I.11 or I.18 causes the fields in their corresponding sections to be read-only.

11. PROTOCOL PREVIOUSLY SUBMITTED TO CVM: ☐ YES ☐ NO
If Yes,   11a. Date Submitted to CVM: 11b. CVM Submission Identifier:

- Clicking the 'YES' button in section I.19 causes the fields in sections I.19a and I.19b to be changeable. Once the 'YES' button is checked the letter 'B' will be displayed in front of the field in section I.19b. The 'Date Submitted to CVM' field in section I.19a is optional, and section I.19b is required. Clicking the 'NO' button in section I.19 causes the fields in sections I.19a and I.19b to be read-only, and the letter 'B' disappears.

19. IS THIS ADDITIONAL INFORMATION FOR A NOTICE PREVIOUSLY SUBMITTED TO CVM:
☐ YES   ☐ NO
If Yes,   19a. Date Submitted to CVM: 19b. CVM Submission Identifier:

NOTICE OF FINAL DISPOSITION OF INVESTIGATIONAL ANIMALS NOT INTENDED FOR IMMEDIATE SLAUGHTER (FDA 3487)

- The form cannot be successfully validated until a value greater than zero is calculated for the 'Total' field in section I.5. This field is calculated as the sum of the 'Treated' and 'Control' fields in section I.5. Entering a value greater than zero into either of these fields will result in successful validation of the required 'Total' field.

5. NUMBER OF ANIMALS:
Total: 0   Treated: 0   Control: 0

- Clicking the 'YES' button in section I.7 will cause the fields in sections I.7a and I.7b to be changeable. Once the 'YES' button is checked the letter 'V' will be displayed in front of the field in section I.7b. The 'Date Submitted to CVM' field in section I.7a is optional, and section I.7b is required. Clicking the 'NO' button in section I.7 causes the fields in sections I.7a and I.7b to be read-only, and the letter 'V' disappears.

7. IS THIS ADDITIONAL INFORMATION FOR A NOTICE PREVIOUSLY SUBMITTED TO CVM:
YES ☐   NO ☐
If Yes,   7a. Date Submitted to CVM: 7b. CVM Submission Identifier:

NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES (FDA 3488)

- The form cannot be successfully validated until a value greater than zero is calculated for the 'Total' field in section I.5. This field is calculated as the sum of the 'Treated' and 'Control' fields in section I.5. Entering a value greater than zero into either of these fields will result in successful validation of the required 'Total' field.

5.	NUMBER OF ANIMALS BEING SLAUGHTERED:		
	Total: 0	Treated: 0	Control: 0

- Clicking the 'YES' button in section I.8 causes the fields in section I.8a and I.8b to be changeable. Once the 'YES' button is checked the letter 'S' will be displayed in front of the field in section I.8b. The 'Date Submitted to CVM' field in section I.8a is optional, and section I.8b is required. Clicking the 'NO' button in section I.8 causes the fields in sections I.8a and I.8b to be read-only, and the letter 'S' disappears.

8.	IS THIS ADDITIONAL INFORMATION FOR A NOTICE PREVIOUSLY SUBMITTED TO CVM:	
	YES ☐ NO ☐	
If Yes,	8a. Date Submitted to CVM:	8b. CVM Submission Identifier:

REQUEST FOR A MEETING OR TELECONFERENCE (FDA 3489)

- You can now schedule a meeting with CVM for multiple Document IDs. Clicking the 'Multiple Documents' checkbox in section A.2 causes the multiple documents table to be displayed at the bottom of the form.

A1. DATE:
A2. MULTIPLE DOCUMENTS: ☒
A3. DOCUMENT ID:

- In the multiple documents table, a user enters the document type, document number, and optionally, the drug name of the document they wish to include in the submission. A user may enter up to 20 Document IDs in the multiple documents table.

Type	Number	Drug Name

Enter up to 20 Document Types and Numbers. Optionally, enter Drug Name.

- All other form data fields will apply to each specified Document ID. You will receive a Sponsor Notification for each Document ID listed in the table.
- Additional command buttons are visible to assist you in filling out the multiple documents table. The commands are: 'Clear All' that clears the multiple documents table; 'Go To Page 1' that returns the user back to the top of page 1; 'Clear Last' that clears the last entry the user made.

Clear All
Go To Page 1
Clear Last

- Additionally, if the 'Check to Amend Meeting Submission' checkbox is selected, the 'Sub ID' column appears and the letter 'Z' is displayed in the column. Here the user must enter the submission number of the submission that is being amended. The user is required to enter a submission to be amended for each Document ID listed in the multiple documents table. If the 'Check to Amend Meeting Submission' checkbox is deselected, the Sub ID column is hidden.

Check to Amend Meeting Submission

Enter up to 20 Document Types and Numbers. Optionally, enter Drug Name.

Type	Number	Sub ID	Drug Name

- If the 'Multiple Documents' checkbox in section A.2 is selected then the 'Document ID' field in section A.3 along with the fields in section I.9 will be hidden. Deselecting the 'Multiple Documents' checkbox will cause these fields to once again be visible.

- Clicking the 'YES' button in section I.9 causes the fields in sections I.9a and I.9b to become changeable. Once the 'YES' button is checked the letter 'Z' will be displayed in front of the field in section I.9b. The 'Date Submitted to CVM' field in section I.9a is optional, and section I.9b is required. Clicking the 'NO' button in section I.9 causes the fields in sections I.9a and I.9b to be read-only, and the letter 'Z' disappears.

9.	MEETING REQUEST PREVIOUSLY SUBMITTED TO CVM:	☒ YES	☐ NO
	If Yes, 9a. Date Submitted to CVM:		9b. CVM Submission Identifier: Z

- **Insert Agenda:** Pressing this command button inserts additional pages from a previously stored PDF file to the submission document. Storage of the agenda within the form will be at the end of the form. The form cannot be successfully validated until a meeting agenda is inserted. Multiple documents may be inserted into the form.

Insert Agenda

PROTOCOL FOR NON-CLINICAL LABORATORY AND EFFECTIVENESS STUDIES (FDA 3536)

- Clicking the 'YES' button in section I.3 causes the fields in sections I.3a and I.3b to be changeable. Once the 'YES' button is checked the letter 'E' will be displayed in front of the field in section I.3b. The 'Date Submitted to CVM' field in section I.3a is optional, and section I.3b is required. Clicking the 'NO' button in section I.3 causes the fields in sections I.3a and I.3b to be read-only and the letter 'E' disappears.

3.	PROTOCOL PREVIOUSLY SUBMITTED TO CVM:	☒ YES	☐ NO
	If Yes, 3a. Date Submitted to CVM:		3b. CVM Submission Identifier: E

- **Insert Protocol**: Pressing this command button inserts additional pages from a PDF file to the submission document at the end of the form. The form cannot be successfully validated until a protocol file is inserted. Multiple documents may be inserted into the form.

Insert Protocol

ELECTRONIC SUBMISSION SYSTEM PARTICIPANT PASSWORD OR ADDITION (FDA 3538)

- Users may select either the checkbox next to section I or the checkbox next to section II.
- If the 'Change Participant's ESS Password:' checkbox is selected the fields in the box directly below section I become changeable, while the fields in the box directly below section II become read-only.
- If the 'Change Participant's ESS Password:' checkbox is selected both the 'Current Password' and 'New Password' fields will accept alpha and numeric and special characters; however, the length of the entry **must** equal 12 characters.

- If the 'Add Participant to ESS:' checkbox is selected the fields in the box directly below section II become changeable, while the fields in the box directly below section I become read-only.
- If the 'Add Participant to ESS:' button is selected the 'Participant One-Time Password' field will accept alpha, numeric and special characters; however, the length of the entry **must** equal 12 characters.

COMPLETING THE FORMS

Complete the following steps when submitting any of the PDF Smart Forms Version 4.1. These steps are generic in nature, and are designed to assist users with completing the forms.

Steps:

1.   Open the desired form.
2.   Fill-in all applicable fields.
3.   On completing data entry, click the 'Validate' button at the bottom of the form to verify that all required fields have been completed.
4.   If any required fields are blank a popup window will list the fields that need to be completed. These empty fields will also be highlighted so that they may be easily located on the form. Once all highlighted fields have been completed, click the 'Validate' button.
5.   If all required fields have been correctly filled-in, a pop-up window will appear to confirm that the form has been successfully validated. If required fields still remain empty, repeat step 3 until the successful validation message appears.
6.   Once the form has been successfully validated, click the 'Add Password' button. A pop-up window will appear and the following steps should be taken:

    Adobe Acrobat 5.0:
    a. Select 'Adobe Standard Security' in the 'Document Security' window.
    b. Select the 'Change Settings' button to open the 'Standard Security' window.
    c. In the 'Specify Password' section, select the 'Password Required to Open Document' checkbox.
    d. Enter your current ESS password in the 'User Password' field.
    e. The user will be asked to re-enter the password for confirmation.
    f. Click the 'Ok' button to close the 'Standard Security' window.
    g. Click the 'Close' button to exit the 'Document Security' window.

    Adobe Acrobat 6.0:
    a. If not selected, choose 'Security' located on the left side of the 'Document Properties' window.
    b. Select 'Password Security' from the 'Security Method' list box.
    c. Click the 'Change Settings' button to open the 'Password Security – Settings' window.
    d. Select 'Acrobat 3.0 and later' from the 'Compatibility' list box.
    e. Select the checkbox labeled 'Require a password to open the document'. The 'Document Open Password' field will become changeable.

    f.   Enter your current ESS password in the 'Document Open Password' field.
    g.   The user will be asked to re-enter the password for confirmation.
    h.   Click the 'Ok' button to close the 'Password Security – Settings' window.
    i.   Click the 'Ok' button to close the 'Document Properties' window.

Adobe Acrobat 7.0:
    a.   If not selected, choose 'Security' located on the left side of the 'Document Properties' window.
    b.   Select 'Password Security' from the 'Security Method' list box.
    c.   Click the 'Change Settings' button to open the 'Password Security – Settings' window.
    d.   Select 'Acrobat 3.0 and later' from the 'Compatibility' list box.
    e.   Select the checkbox labeled 'Require a password to open the document'. The 'Document Open Password' field will become changeable.
    f.   Enter your current ESS password in the 'Document Open Password' field.
    g.   The user will be asked to re-enter the password for confirmation.
    h.   Click the 'Ok' button to close the 'Password Security – Settings' window.
    i.   Click the 'Ok' button to close the 'Document Properties' window.

7.   Once a password has been applied to the form click the 'Save' button. Note: Changes to document security will not take affect until the form has been saved.
8.   **The 'Signature' button is currently disabled.**
9.   Click the 'Send to CVM' button to email the form. If the user has successfully validated the form, applied a password, and saved the form, the default email application will appear and a new email message will be created. The message will be automatically addressed to cvmdcu@fda.gov, and the name of the form will appear in the subject line. The completed form will be an attachment to the message. Click the 'Send' button to submit the form to CVM.